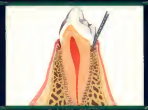
STAGES OF PERIODONTAL DISEASE

Healthy Gums

Firm and resilient tissue characterized by minimal sulcus depth and coral pink coloring. Variations in gingival color may occur depending on patient's complexion and race. Evidence of previous disease may be present.





Product Options



Each of the above is available over the counter. The dentifrices are all indicated for caries protection. Sensitivity Protection Crest is indicated for tooth sensitivity. Crest Gum Care is indicated for the treatment of gingivitis.

Gingivitis

Inflammation of the gingiva characterized clinically by changes in color, gingival form, position, surface appearance, and presence of bleeding and/or exudate.







An OTC product that reduces mild to moderate gingivel inflammation and gingivel bleeding while also providing caries protection.

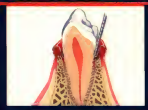


A prescription product indicated for the adjunctive treatment of gingivitis characterized by gingivel bleeding and inflammation.* Peridex may cause supragingival calculus formation and orel surface staining. Crest Gum Care and Peridex are not currently recommended for concurrent usage. (See full prescribing information attached.)

Periodontitis:

Early

Progression of the gingival inflammation into the deeper periodontal structures and alveolar bone crest, with slight bone loss. There is usually a slight loss of connective tissue attachment and alveolar bone.*

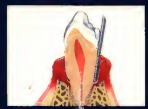






Moderate

A more advanced stage of the previous condition, with increased destruction of the periodontal structures and noticeable loss of bone support, possibly accompanied by an increase in tooth mobility. There may be furcation involvement in multi-rooted teeth.*





is indicated as an adjunct to Scaling and Root Planing for the reduction of pocket depth and bleeding on probing in patients with adult periodontitis.*

The most common adverse reactions are limited to local erythema on removal (11% incidence) and discomfort on placement (10% incidence). Peridex and Crest Gum Care are not indicated for periodontitis. The effect of Peridex and Crest Gum Care on periodontitis has not been determined.

Advanced

Further progression of periodontitis with major loss of alveolar bone support, usually accompanied by increased tooth mobility. Furcation involvement in multi-rooted teeth is likely.*





Advanced Periodontitis is an extreme condition. Patients should immediately seek the care of a dental professional.

***Your dentist should recommend the appropriate therapy and product to treat your condition.**

*Reprinted with permission from the American Academy of Periodontology. Current Procedural Terminology for Periodontitis and Insurance Report Manual, 6th edition.

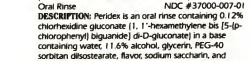
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PERIDEX®

(CHLORHEXIDINE GLUCONATE 0.12%)

PERIDEX®
(CHLORHEXIDINE GLUCONATE 0.12%)
Oral Rinse NDC #37000-007-01

DESCRIPTION: Peridex is an oral rinse containing 0.12% chlorhexidine gluconate (1, 1'-hexamethylene bis [5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Peridex is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its chemical structure is:



CLINICAL PHARMACOLOGY:
Peridex provides microbicidal activity during oral rinsing. The clinical significance of Peridex's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% through six months' use.

Use of Peridex in a six-month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after Peridex use was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at baseline.

PHARMACOKINETICS: Pharmacokinetic studies with Peridex indicate approximately 30% of the active ingredient, chlorhexidine gluconate, is retained in the oral cavity following rinsing. This retained drug is slowly released into the oral fluids. Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate reached a peak of 0.206 µg/g in humans 30 minutes after they ingested a 300-mg dose of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the feces (~90%). Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

INDICATION: Peridex is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Peridex has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

CONTRAINDICATIONS: Peridex should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate.

WARNINGS: The effect of Peridex on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in Peridex users compared with control users. It is not known if Peridex use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months.

Rare hypersensitivity and generalized allergic reactions have also been reported. Peridex should not be used by persons who have a sensitivity to it or its components.

PRECAUTIONS:
GENERAL:

1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with Peridex should not be used as a major indicator of underlying periodontitis.
2. Peridex can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining. In clinical testing 56% of Peridex users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months. 15% of Peridex users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque.

   Stain resulting from use of Peridex does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis.

   Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from Peridex treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.
3. Some patients may experience an alteration in taste perception while undergoing treatment with Peridex. Most patients accommodate to this effect with continued use of Peridex. No instances of permanent taste alteration due to Peridex have been reported.

USAGE IN PREGNANCY: Pregnancy Category B.
Reproduction and fertility studies with chlorhexidine gluconate have been conducted. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day, and no evidence of harm to the fetus was observed in rats and rabbits at doses up to 300 mg/kg/day and 40 mg/kg/day, respectively. These doses are approximately 100, 300, and 40 times that which would result from a person's ingesting 30 ml (2 capfuls) of Peridex per day. Since controlled studies in pregnant women have not been conducted, the benefits of the drug in pregnant women should be weighed against possible risk to the fetus.

NURSING MOTHERS: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Peridex is administered to a nursing woman.

In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a person's ingesting 30 ml (2 capfuls) of Peridex per day.

PEDIATRIC USE: Clinical effectiveness and safety of Peridex has not been established in children under the age of 18.

CARCINOGENESIS, MUTAGENESIS: In a drinking water study in rats, carcinogenesis was not observed. The highest dose of chlorhexidine gluconate used in this study, 38 mg/kg/day, is at least 500 times the amount that would be ingested from the recommended daily dose of Peridex.

In two mammalian *in vivo* mutagenic studies with chlorhexidine gluconate, mutagenesis was not observed. The highest dose of chlorhexidine gluconate used in a mouse dominant lethal assay was 1000 mg/kg/day and in a hamster cytogenetics test was 250 mg/kg/day, i.e., >3200 times the amount that would be ingested from the recommended daily dose of Peridex.

ADVERSE REACTIONS: The most common side effects associated with chlorhexidine gluconate oral rinses are (1) an increase in staining of teeth and other oral surfaces, (2) an increase in calculus formation, and (3) an alteration in taste perception; see WARNINGS and PRECAUTIONS. No serious systemic adverse reactions associated with use of Peridex were observed in clinical testing.

Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using Peridex, particularly among children.

Although there have been no reports of parotitis (inflammation or swelling of salivary glands) among Peridex users in controlled clinical studies, transient parotitis has been reported in research studies with chlorhexidine-containing mouthrinses.

OVERDOSAGE: Ingestion of 1 or 2 ounces of Peridex by a small child (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of Peridex is ingested by a small child or if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION: Peridex therapy should be initiated directly following a dental prophylaxis. Patients using Peridex should be reevaluated and given a thorough prophylaxis at intervals no longer than six months.

Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 1/2 fl.oz. (marked in cap) of undiluted Peridex. Peridex is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED: Peridex is supplied as a blue liquid in dispenser packs of three 1-pint amber plastic bottles with child-resistant dispensing closures. Store above freezing (32°F).

Revised April 1988
Made by Procter & Gamble
Cincinnati, Ohio 45202

PERIDEX®
(chlorhexidine gluconate 0.12%)
ORAL RINSE

WHAT TO EXPECT WHEN USING PERIDEX
Your dentist has prescribed Peridex Oral Rinse to treat your gingivitis — to help reduce the redness and swelling of your gums, and also to help you control any gum bleeding. Use Peridex regularly, as directed by your dentist, in addition to daily brushing and flossing.

Peridex may cause some tooth discoloration, or increases in tartar (calculus) formation, particularly in areas where plaque is more difficult to remove with normal brushing alone. It is important to see your dentist for removal of any stain or tartar at least every six months, or more frequently if your dentist advises.

- Both stain and tartar can be removed by your dentist or hygienist. Peridex may cause permanent discoloration of some front-tooth fillings.
- To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
- Rare hypersensitivity and generalized allergic reactions have also been reported. Peridex should not be used by persons who have a sensitivity to it or its components.

Peridex may taste bitter to some patients and can affect how foods and beverages taste. This will become less noticeable in most cases with continued use of Peridex. After treatment with Peridex has ended, taste perception will be normal.

- To avoid taste interference, rinse with Peridex after meals. Do not rinse with water immediately after rinsing with Peridex as this will increase the bitter aftertaste.

If you have any questions or comments about Peridex, contact your dentist or pharmacist.